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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,624	03/28/2002	Ikuro Maruyama	0760-0298P	8158

2292 7590 06/08/2004

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,624	MARUYAMA ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1-14, 17-19 drawn to an adsorbent bearing hydrogen-bondable functional groups and/or hydrophobic functional groups.
2. Claims 15-19, drawn to an adsorbent bearing antibodies to an HMG protein.
3. Claims 20-22, drawn to a column which contains an adsorbent according to Group 1
4. Claims 20-22, drawn to a column which contains an adsorbent according to Group 2.
5. Claims 23-27, drawn to a method of using the Group 1 adsorbent to adsorb HMG proteins from body fluid.
6. Claims 23-27, drawn to a method of using the Group 2 adsorbent to adsorb HMG proteins from body fluid.

Claims 28-39 are not grouped. In the event that these claims are amended to recite a statutory class of invention in accordance with U.S. practice, these claims will be grouped appropriately.

The claimed inventions are distinct.

Groups 1 and 2 are distinguished in that Group 1 requires specific functional groups (e.g.,

sulfonate, carboxylate or phenyl groups) that permit adsorption by electrostatic attraction, or hydrophobic interaction. Such forces are also present in the case of antibody/antigen binding, but they are more specific in the latter case, and a wide variety of functional groups are present in the case of antibodies as well.

Inventions {3, 4} and {1, 2} are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because. However, in the event that either of Groups 1 or 2 is elected, and claims therein found allowable, claims drawn to a column which contains the allowable adsorbent will be rejoined for further examination.

Inventions {1, 2} and {5, 6} are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). The adsorbent can be used, e.g., for isolating and purifying specific HMG proteins. However, in the event that either of Groups 1 or 2 is elected, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further

examination (subject to the same limitations on the adsorbent)

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that Group 1 is chosen for initial examination, the species to be elected are the following:

(a) a specific water-insoluble carrier such as agarose or dextran, or ceramic coated with polystyrene, or glass coated with a polysulfone;

(b) a statement as to which of the following applies: (i) hydrogen-bondable functional groups are immobilized on the adsorbent, and at the same time, hydrophobic functional groups are not immobilized on the adsorbent; (ii) hydrophobic functional groups are immobilized on the adsorbent, and at the same time, hydrogen-bondable functional groups are not immobilized on the adsorbent; or (iii) hydrogen-bondable functional groups are immobilized on the adsorbent, and hydrophobic functional groups are also immobilized on the adsorbent;

(c) in the event that (b)(i) applies, an election of a specific hydrogen-bondable functional group that is immobilized on the adsorbent, accompanied by a statement as to whether the hydrogen-bondable functional group is bonded directly to the water-insoluble carrier, or whether it is bonded via a linker. If bonded via a linker, what is the linker? Also required is an election of a specific means of bonding of the functional group to the carrier or to the linker (e.g., cyanogen bromide activation, or carbodiimide activation)

(d) in the event that (b)(ii) applies, an election of a specific hydrophobic functional group that is immobilized on the adsorbent, accompanied by a statement as to whether the hydrophobic functional group is bonded directly to the water-insoluble carrier, or whether it is bonded via a linker. If bonded via a linker, what is the linker? Also required is an election of a specific means of bonding of the functional group to the carrier or to the linker (e.g., cyanogen bromide activation, or carbodiimide activation)

(e) in the event that (b)(iii) applies, an election of a specific hydrophobic functional group that is immobilized on the adsorbent, accompanied by a statement as to whether the hydrophobic functional group is bonded directly to the water-insoluble carrier, or whether it is bonded via a linker. If bonded via a linker, what is the linker? Also required is an election of a specific hydrogen-bondable functional group that is immobilized on the adsorbent, accompanied by a statement as to whether the hydrogen-bondable functional group is bonded directly to the water-insoluble carrier, or whether it is bonded via a linker. If bonded via a linker, what is the linker? Also required is an election of a specific means of bonding of the functional group to the carrier or to the linker (e.g., cyanogen bromide activation, or carbodiimide activation)

(f) an election of a specific "form" of the adsorbent (when dry), e.g., a fiber, a hollow fiber, beads, a flat membrane, or a powder (page, 6, line 20, specification).

. . . . .

In the event that Group 2 is chosen for initial examination, the species to be elected are the following:

(a) a type of antibody, i.e., IgG, IgA, IgE or IgM, and a statement as to whether the antibody is monoclonal or polyclonal, and a statement as to which HMG protein the antibody has been raised against;

(b) a statement as to whether the antibody is bonded directly to the water-insoluble carrier, or whether it is bonded via a linker. If bonded via a linker, what is the linker? Also required is an election of a specific means of bonding of the functional group to the carrier or to the linker (e.g., cyanogen bromide activation, or carbodiimide activation);

(c) an election of a specific "form" of the adsorbent (when dry), e.g., a fiber, a hollow fiber, beads, a flat membrane, or a powder (page, 6, line 20, specification).

. . . .

In the event that Group 3 is chosen for initial examination, the species to be elected are the same as that for Group 1.

. . . .

In the event that Group 4 is chosen for initial examination, the species to be elected are the same as that for Group 2.

. . . .

In the event that Group 5 is chosen for initial examination, the species to be elected are the same as that for Group 1. Four additional species elections are required as well: (i) a specific body fluid (e.g., serum or whole blood) from which the HMG proteins are to be removed, (ii) a fully described "column" that is intended to remove substances originating from bacteria, (iii) a specific HMG protein (e.g., HMG-1) that is to be removed from the body fluid, and (iv) a specific substance that is produced by bacteria, and which applicants intend, via the process of claim 27, to remove from the body fluid.

. . . .

In the event that Group 6 is chosen for initial examination, the species to be elected are the same as that for Group 2. Four additional species elections are required as well: (i) a specific body fluid (e.g., serum or whole blood) from which the HMG proteins are to

be removed, (ii) a fully described "column" that is intended to remove substances originating from bacteria, (iii) a specific HMG protein (e.g., HMG-1) that is to be removed from the body fluid, and (iv) a specific substance that is produced by bacteria, and which applicants intend, via the process of claim 27, to remove from the body fluid.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise

include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

✷

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1653